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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/840,131	05/06/2004	Matthew Iammatteo	Lifeline Medical	7250

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EXAMINER	
HUI, SAN MING R	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 05/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/840,131	IAMMATTEO, MATTHEW	
	Examiner	Art Unit	
	San-ming Hui	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 January 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *9-16 and 21-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 17-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 9-16 and 21-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on August 9, 2004.

Applicant's remarks with regard to the restriction requirements, especially the rejoinder remarks, have been considered, but are not found persuasive. Examiner notes that it is incorrect for the Examiner to sua sponte rejoin the non-elected claims prior to issuing final rejection. Non-elected invention will only be rejoined after the composition claims in condition of allowance provided that the scope of the non-elected invention is the same as the claims directed to the allowed composition.

Claim Rejections - 35 USC § 102

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-3, 6, 17-18, and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Bell et al. (US2003/0139381).

Bell et al. teaches a composition comprising estrogen, progesterone and fluoxetine (See claims 48, 69, and 73 for example).

Response to Arguments

Applicant's arguments filed January 5, 2006 averring the cited prior arts' failure to teach the three-part combination have been considered, but are not found persuasive. The instant claimed product comprising three components: estrogen, progesterone, and a SSRI. Bell et al., teaches a kit, which is a product, comprising estrogen, progesterone, and a SSRI. Therefore, the cited prior art teaches the exact product as claimed. Examiner notes that the instant claims do not recite the three components must be in a single composition. The claims recite a product, which is construed as a kit.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4-5, 7-8, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bell et al.

Bell et al. teaches a composition comprising estrogen, progesterone and fluoxetine (See claims 48, 69, and 73 for example). Bell also teaches the pharmaceutical composition may be formulated into transdermal patch and vaginal ring (See paragraph [0039]).

Bell et al. does not expressly teach the product as formulated into transdermal patch and intra-vaginal ring.

It would have been obvious to one of ordinary skill in the art at the time of invention to formulate the composition of Bell into transdermal patch and vaginal ring.

One of ordinary skill in the art would have been motivated to formulate the composition of Bell into transdermal patch and vaginal ring. Since the composition of Bell can be formulated into transdermal patch and vaginal ring, it would be obvious to one of ordinary skill in the art to formulate the composition into either pharmaceutical dosage forms as the selection of one or another known pharmaceutical dosage form would be seen as a simple selection from among obvious alternatives.

Claims 1-4, 6-7, and 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Studd et al., (Advances in Gynecological Endocrinology, 12/2000, pages 83-89) and Freeman et al., (Archives of General Psychiatry, 1999;56(10):932-939).

Studd et al. teaches a method of employing estrogen patch and progesterone to treat Premenstrual syndrome (See pages 84-85).

Freeman et al. teaches selective serotonin reuptake inhibitors as useful in treating premenstrual syndrome (See the abstract).

The primary references do not expressly teach a composition comprising estrogen, progesterone, and selective serotonin reuptake inhibitors.

It would have been obvious to one of ordinary skill in the art at the time of invention to incorporate estrogen, progesterone, and selective serotonin reuptake inhibitors into a single composition.

One of ordinary skill in the art would have been motivated to incorporate estrogen, progesterone, and selective serotonin reuptake inhibitors into a single composition. Combining two or more agents which are known to be useful to treat premenstrual syndrome individually into a single composition useful for the very same purpose is prima facie obvious (See *In re Kerkhoven* 205 USPQ 1069). Furthermore, formulating the combination composition into a transdermal patch or oral formulation would be obvious as the selection of one or another known pharmaceutical dosage form would be seen as a simple selection from among obvious alternatives.

Claims 5 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Studd et al. and Freeman et al. as applied to claims 1-3, 6, 17-18, and 20 above, and further in view of Bell et al.

Studd and Freeman suggest a composition comprising estrogen, progesterone, and selective serotonin reuptake inhibitors.

Studd and Freeman do not expressly teach the product as formulated into transdermal patch and intra-vaginal ring.

Bell et al. teaches a composition comprising estrogen, progesterone and fluoxetine (See claims 48, 69, and 73 for example). Bell also teaches the pharmaceutical composition may be formulated into transdermal patch and vaginal ring (See paragraph [0039]).

It would have been obvious to one of ordinary skill in the art at the time of invention to formulate estrogen-progesterone-selective serotonin reuptake inhibitors composition into vaginal ring.

One of ordinary skill in the art would have been motivated to formulate estrogen-progesterone-selective serotonin reuptake inhibitors composition into vaginal ring. Since vaginal ring is known to be useful in delivering estrogen-progesterone-selective serotonin reuptake inhibitors composition according to Bell et al., one of ordinary skill in the art would have been reasonably expected to be effective in formulating estrogen, progesterone, and selective serotonin reuptake inhibitors into vaginal ring. The selection of one or another known pharmaceutical dosage form would be seen as a simple selection from among obvious alternatives.

Response to Arguments

Applicant's arguments filed January 5, 2006 averring the cited prior arts' failure to provide the motivation to formulate the components into different recited dosage forms have been considered, but are not found persuasive. The herein claimed dosage forms

are considered conventional dosage forms for delivering the hormonal components. Selecting one over the other conventional dosage forms is considered obvious as being within the purview of the skilled artisan, absent evidence showing the criticality of the specific dosage forms employed.

Applicant's arguments filed January 5, 2006 averring the teaching away in the cited prior arts have been considered, but are not found persuasive. Specifically, the declaration by Dr. Iammatteo filed January 5, 2006 citing the teaching of Studd et al., alleging Studd for teaching away have been considered, but are not found persuasive. Examiner notes that the method taught by Studd to treat PMS is not progesterone alone. Rather, the method employs both estrogen and progesterone. Taking the teachings of Freeman together, one of ordinary skill in the art would have been motivated to employ all the herein recited components together in a product to treat PMS since the composition of Studd and that of Freeman are known to be useful in treating PMS individually. Combining the composition of Studd and Freeman into a single product or composition useful for the very same purpose would be prima facie obvious, absent evidence to the contrary.

Applicant's arguments filed January 5, 2006 averring the unexpected results shown in declaration filed January 5, 2006 have been considered, but are not found persuasive. The study is not a double-blinded study. Also the method as to how to assess the clinical outcome is not known. It is not clear what has been measured in terms of the clinical endpoints. Furthermore, Examiner notes that the study does not administer a single composition containing all three components to the patients. Dr.

Iammatteo merely uses drug combinations, using two separate pharmaceutical products, in the study. In addition, the study does not even compare to the SSRI alone or the estrogen and/or progesterone alone with the combination. In view of the teachings of the cited prior arts, the combination of estrogen, progesterone, and a SSRI is expected to be effective in treating PMS. Therefore, unexpected benefits are not seen herein.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax

phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

San-ming Hui
Primary Examiner
Art Unit 1617